

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**

## REMARKS

Claims 10-20 and 38-62 are pending in the instant application. Claims 10-14, 16, 17, 19, 20, 38-46, 50-54 and 60 have been amended to clarify the claimed invention. Per the suggestion by Examiner Canella, claims 14, 17, 19, 42 and 52-54 have been amended to recite "antibody" rather than "protein." Claims 10-13, 16, 38-41, 43-45, 50, 51 and 60 have been amended, for clarification purposes, to recite a protein "chain" rather than "protein" (since, for example, a nucleic acid could encode a heavy or light chain of an antibody). Claim 46 has been amended to delete dependencies from claims 38, 42 and 45. New claim 63 has been added. Support for amendments of the claims listed below and new claim 63 can be found in the specification of the application, as outlined in the following table:

<u>CLAIM(S)</u>	<u>SUPPORT IN SPECIFICATION</u>
10-12	Page 5, lines 27-30; page 6, lines 32-34; page 7, lines 1-3; page 12, lines 26-29; page 13, lines 8-10
13	Page 5, lines 27-30; page 6, lines 5-8, 32-34; page 7, lines 1-3; page 12, lines 26-29; page 13, lines 8-10; page 30, lines 26-33
14	Page 12, lines 26-29; page 13, lines 8-10; page 25, lines 14-16
16	Page 5, lines 27-30; page 6, lines 32-34; page 7, lines 1-3; page 12, lines 26-29; page 13, lines 8-10
17, 19	Page 12, lines 26-29; page 13, lines 8-10; page 25, lines 14-16
38	Page 12, lines 26-33; page 13, lines 8-10; Example 7
39	Page 5, lines 27-30; page 6, lines 5-8, 32-34; page 7, lines 1-3; page 12, lines 26-29; page 13, lines 8-10; page 30, lines 26-33
40	Page 5, lines 27-30; page 6, lines 32-34; page 7, lines 1-3; page 12, lines 26-29; page 13, lines 8-10
41	Page 5, lines 27-30; page 6, lines 32-34; page 7, lines 1-3; page 12, lines 26-29; page 13, lines 8-10
42	Page 12, lines 26-29; page 13, lines 8-10; page 25, lines 14-16
43-45	Page 5, lines 27-30; page 6, lines 32-34; page 7, lines 1-3; page 12, lines 26-29; page 13, lines 8-10
46	Page 5, lines 25-26
50	Page 5, lines 27-30; page 6, lines 32-34; page 7, lines 1-3; page 12, lines 26-29; page 13, lines 8-10

51	Page 5, lines 27-30; page 6, lines 32-34; page 7, lines 1-3; page 12, lines 26-29; page 13, lines 8-10
52-54	Page 12, lines 26-29; page 13, lines 8-10; page 25, lines 14-16
60	Page 5, lines 27-30; page 6, lines 32-34; page 7, lines 1-3; page 12, lines 26-29; page 13, lines 8-10
63	Page 34, lines 2-3; Example 7

No new matter has been added.

Upon entry of the amendments made herein, claims 10-20 and 38-63 will be pending in the present application.

The pending Office Action Summary indicates that claims 13, 39-41 and 46-49 currently stand rejected. The Office Action Summary also states that claims 10-12, 14-20, 38, 42-45 and 50-62 are allowed. Applicants note, however, that the Office Action states that claims 14 and 42 also stand rejected under 35 U.S.C. § 112, first paragraph. Moreover, during the Interview of May 6, 2003, as noted above, Examiner Canella indicated that the rejection of claims 14 and 42 under 35 U.S.C. § 112, first paragraph, should also be applied to claims 17, 19, 46-49 and 52-54. Applicants therefore proceed on the assumption that claims 13, 14, 17, 19, 39-42, 46-49 and 52-54 stand rejected, and that claims 10-12, 15, 16, 18, 38, 43-45, 50, 51 and 55-62 are allowed.

#### THE REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

The Examiner has rejected claims 13 and 39-41 under 35 U.S.C. § 112, second paragraph as indefinite. The Examiner believes that the recitation in these claims of "Blastp" renders these claims indefinite because "Blastp" is a trade name and is therefore an object that is variable. As suggested by the Examiner in the Interview of May 6, 2003, Applicants have amended claims 13, 39 and 40 to delete reference to the term "Blastp," thus obviating the rejection. This amendment applies as well to claim 41, which depends from claim 40. Applicants respectfully request that the Examiner withdraw the rejection of these claims on this basis.

The Examiner has also rejected claims 46-49 under 35 U.S.C. § 112, second paragraph as indefinite. The Examiner contends that claim 46 fails to further limit claims 35 [sic, 38]-45, since the encoded proteins of claims 38-45 are antibody in nature. Applicants, following the Examiner's suggestion to remove dependencies on claims 38 and 45, have

amended claim 46 to depend solely from claims 39-41, 43 and 44. (The dependency from claim 42 was deleted, since claim 42 was amended to specify an antibody heavy chain.) Each of these claims, as currently amended, specifies that the recited nucleotide sequence encodes a *chain of a protein* having a particular antibody-related sequence or sequences. Thus, these claims encompass nucleotide sequences that encode not just antibodies, but also antibody-related molecules such as antibody derivatives and analogs, antibody fragments, etc. Claim 46, however, specifically recites that the protein of claims 39-44 is an antibody. Thus, claim 46, and claims 47-49, which depend from claim 46, further limit the scope of claims 39-44. Applicants respectfully request that the Examiner withdraw the rejection of claims 46-49 on this basis.

#### THE REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

The Examiner has rejected claims 14 and 42 under 35 U.S.C. § 112, second paragraph as lacking written description support. During the May 6, 2003 Interview, Examiner Canella indicated that claims 17, 19, 42, 46-49 and 52-54 should also be rejected on this basis.

The Examiner contends that, while the claims encompass a genus of nucleic acids that encode a protein that binds CD40, the specification discloses only an antibody comprising the variable regions of SEQ ID NO: 7 and SEQ ID NO: 2 that comprises the CDR sequences of SEQ ID NOS: 8-10. The Examiner contends that, because the claims are not defined in terms of nucleic acid sequences, but only in terms of function, that is, encoding a protein having a particular activity, that the claims fail to meet the written description requirement of 35 U.S.C. § 112, first paragraph.

Applicants have amended claims 14, 17, 19 and 42 to recite that the nucleotide sequence encodes an antibody heavy chain. Because claims 46-49 depend from claim 42, the amendment to claim 42 applies to these claims, as well. Finally, Applicants have also amended claims 52-54, which depend from claims 14 and 42, to conform to those claims' recitation of "antibody heavy chain" rather than "protein."

As indicated in the Office Action, a claimed genus must be supported by a description of relevant identifying characteristics of a representative number of species. *Regents of University of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), *cert. denied* 523 U.S. 1089 (1998). What constitutes a "representative number of species" depends upon the knowledge and skill in the art. *Eli Lilly*, 119 F.3d at 1568. The description is deemed sufficient if it demonstrates to the skilled artisan that the applicant was in possession of the necessary common attributes of the members of the genus. *Eli Lilly*, 119 F.3d at 1568. There

is no requirement that the *claims* recite a particular nucleotide sequence, only that the genus of nucleotide sequences be adequately described in the specification.

The claims as amended satisfy the PTO's criteria for written description. For the PTO's interpretation of written description support for protein claims, the Examiner is invited to review the Revised Interim Written Description Guidelines Training Materials ("Guidelines") published in the PTO web site (<http://www.uspto.gov/web/menu/written.pdf>). In particular, Example 16 in the guidelines is instructive. In Example 16, the claim "An isolated antibody capable of binding to antigen X" is deemed to be supported by the disclosure of protein X, described as 55 kDa and useful for the detection of HIV, where the specification contemplates but does not teach an example of an antibody that specifically binds protein X. The PTO concludes that the disclosure *does* meet the requirements of 35 U.S.C. § 112, first paragraph, as providing adequate written description because of: (i) the routine art-recognized method of making antibodies to fully-characterized antigens; (ii) the well-defined structural characteristics for the five classes of antibodies, (iii) the functional characteristics of antibody binding; and (iv) the fact that antibody technology is well-developed and mature. As a result, the PTO states, "one of skill in the art would have recognized that the spectrum of antibodies which bind to antigen X were implicitly disclosed as a result of the isolation of antigen X." (Page 60).

For similar reasoning, there is adequate written description for claims 14, 17, 19 and 42. As amended, these claims are directed to a nucleotide sequence that encodes an antibody heavy chain; an antibody heavy chain is a well-defined structure having known, well-defined structural characteristics. Additionally, the claims recite the functional characteristics of the antibody heavy chains; claim 42 recites that the antibody binds to CD40 (and has other functional and structural characteristics), and claims 14, 17 and 19 recite that the antibody competes with antibody S2C6 for binding to the antigen CD40. Because antibody binding characteristics are determined by an antibody's structure, these recitations represent structural limitations. The level of skill in the art of antibody production and recombination is also high, and the art is well-developed.

Nucleotide sequences encoding the desired antibody heavy chain sequences are readily obtainable through the use of a codon table, and would be apparent to one of skill in the art. Moreover, the recitation in claim 14, 17 and 19 of "competes for binding to CD40 with monoclonal antibody S2C6 as secreted by the hybridoma deposited with the ATCC and assigned accession number PTA-110" ensures that the claimed nucleotide sequence of these claims encodes an antibody heavy chain having a binding domain structure and conformation

common to the genus. Thus, the instant specification is sufficient to describe the claimed genus of nucleic acids.

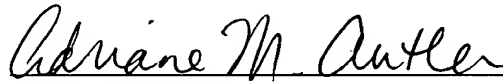
Therefore, the requirement in *Eli Lilly* that the description be sufficient to demonstrate possession of the invention is satisfied by the current disclosure. In view of the foregoing, Applicants respectfully request that the Examiner withdraw the rejection of claims 14 and 42, and the presumptive rejection of claims 17, 19, 46-49 and 52-54, under 35 U.S.C. § 112, first paragraph, for lack of written description.

#### CONCLUSION

Applicants respectfully request consideration of the foregoing remarks and entry of the foregoing amendments into the file of the above-identified application. Applicants believe that each ground for rejection has been successfully overcome or obviated, and that all the pending claims are in condition for allowance. Withdrawal of the Examiner's rejections and allowance of the application are respectfully requested.

Respectfully submitted,

Date: July 28, 2002

  
Adriane M. Antler 32,605  
(Reg. No.)  
**PENNIE & EDMONDS LLP**  
1155 Avenue of the Americas  
New York, New York 10036-2711  
(212) 790-9090  
Enclosures